REMARKS

Preliminary Remarks

Claims 1, 3-7, 9, 10, 14-26 and 28-32 were rejected in the Final Office Action dated September 30, 2009. Claims 14-19 and 24-25 are canceled at this time; only claim 30 is currently amended, to correct an error in dependency.

A 37 CFR 1.132 declaration of Dr. James D. Lewis (an inventor of both the Myers et al. reference, U.S. Patent 5,628,782 and of the present application) is being submitted with this response, in regard to the 35 USC 102 rejections over the Myers et al. and Tu et al. references, discussed further below. Applicants would like to have this declaration on record prior to filing an appeal brief, if that is subsequently deemed necessary.

Double Patenting

The Examiner has advised that should claim 24 be found allowable, claim 28 will be objected to as being a substantial duplicate thereof. While Applicants' position is that the claims are meaningfully different, claim 24 is now canceled.

Rejections under 35 U.S.C. §102

I. Claims 1, 3-7, 9, 10, 14-16, 19, 20, 23-26 and 28-30 are rejected under 35 U.S.C. §102(e) as being anticipated by Myers et al. (US 5,628,782).

Myers et al. teach the construction of a tubular vascular graft intended for use with dialysis patients; the vascular graft is preferably made of ePTFE and includes a covering of material in a form to inhibit bleeding following removal of a dialysis needle after the tube has been punctured with the needle. This vascular graft is based on commercially available, film-reinforced ePTFE GORE-TEX® Vascular Grafts (col. 11, lines 36-42).

Applicants respectfully disagree with the rejections, particularly with regard to claim 1 (the sole independent claim). The points of disagreement are addressed in the sequence that they were raised by the Examiner.

The Examiner notes that the use of "substantially unchanged" is terminology of relative degree, which has no basis of comparison, and that consequently it is considered broad and relatively unlimited. Applicants' disagree with this "broad and relatively unlimited" interpretation. First, the specification provides appropriate support for the use of "substantially unchanged" in that it gives various examples that describe the changes of circumference resulting from the application of increasing pressure up to the second circumference and the minimal diameter change of circumference that occurs additionally with further increasing pressure (e.g., example 6 on page 20). Further, as the Examiner undoubtedly appreciates, there is considerable precedent for the legitimate and similar use of "substantially" in US patent claims. See, for example, *Playtex Products, Inc. v. Proctor & Gamble Co.,* 400 F.3d 901, 73 U.S.P.Q.2d [BNA] 2010 (Fed. Cir. 2005).

The Examiner asserts that the claimed physical property of the tube (in this case, a substantially unchanged second circumference upon expansion 100%) is present in Myers et al. even though not explicitly recited. He adds that "Since the material of the tube is the same as what is being claimed, the blood liner [it appears that "vascular graft" was intended, referring to the tube of Tu et al., rather than "blood liner"] inherently possesses the same unchanged second circumference in response to internal pressure as the claimed blood conduit liner tube. The Examiner's assertion is unfounded; engineering is fundamentally about using materials in various ways to provide variously different attributes. To say that the tube of the present invention, made from materials very similar to those of the Myers et al. vascular graft, has of necessity the same performance properties, is somewhat analogous to saying that a Boeing 737 and a beer can, both being of aluminum and having tubular aspects, must therefore have similar aerodynamic properties. The present specification teaches in considerable detail how the porous PTFE materials are processed and assembled (engineered) to achieve the claimed pressure performance attributes of the present blood conduit liner that are entirely different from those of the vascular graft of Myers et al. (or of other tubes designated for use as "vascular grafts"). Similar materials are used in Myers et al. and in the present invention because of their long, successful history of safe and effective use as blood contact materials; indeed ePTFE is preferred without other materials, as generally taught in the present invention, due to the superior biocompatibility of this material). The necessary fundamental pressure related performance differences are due to the entirely different requirements of a vascular graft such as taught by Myers et al. (wherein any appreciable

distensibility is not only undesirable but unacceptable), versus the requirements of a distensible intraluminal graft (blood conduit liner) which is intended to be inserted into vasculature at a small diameter and deployed by the use of applied internal pressure to the larger diameter of the inside of the vessel into which it is intended to be fitted, and is intended to be resistant to further dilatation much beyond this diameter. Please see the appended declaration of James D. Lewis for further explanation.

Regarding claims 3 and 4 (claims 15 and 16 now being canceled), the Examiner asserts that Myers et al. also disclose the liner comprising a wall thickness less than 0.25mm and can be about 0.1mm thick, at col. 15, lines 50, 51. This is a misinterpretation of Myers et al. The cited text teaches that "The porous films used to make examples of the present invention had a thickness of about 0.01mm..." Myers et al. are thus describing the thickness of film components used to make their vascular graft and not the wall thickness of the graft itself. Claims 3 and 4 are directed to the wall thickness of the claimed liner; Myers et al. do not teach that the wall of their vascular graft can be as thin as 0.25mm.

Regarding claim 29, it is stated that, according to Myers et al., the liner can be a living blood vessel (col. 3, lines 59-62). While Myers et al. do teach that the base substrate of their vascular graft can be of biologic material, claim 29 is not directed to such. Rather, this claim specifies the blood conduit liner of wherein the blood conduit (*not the blood conduit liner*) is a living blood vessel; i.e., that the liner is intended to line a living vessel. This is different from the teaching of Myers et al. that a component of their vascular graft may be of biologic material.

Regarding claim 30, it is stated that Myers et al. disclose that an anastomosis can be a site of a repair (col. 14, lines 11-37). Claim 30 specifies that the liner covers an anastomosis. This use of a liner to cover an anastomosis is entirely different from the cited teaching of Myers et al. that relates to sewing the ends of a vascular graft to incisions in an artery and a vein. This teaching does not describe or suggest the use of any sort of prosthetic covering over the resulting anastomosis.

II. Claims 1, 5, 9, 10, 14, 17, 19, 20, 22-26, and 28-31 are rejected under 37 U.S.C. §102(b) as being anticipated by Tu et al. (US 5,061,276).

Tu et al. teach the construction of a vascular graft comprising an inner layer of PTFE and an outer layer of PTFE blended with an elastomer, with the two layers being co-extruded (see steps 1-3 of the manufacturing process, col. 9, line 30 to col. 10, line 18, also related description of Figure 2 at col. 12, lines 19-21). The elastomer of the outer layer "...provides elasticity to improve compliance..." (col. 10, lines 9-11) and as such is essential to the performance of the compliant vascular graft of Tu et al. The graft may optionally and preferably be applied with outer covering(s) of elastomeric materials in the form of fibers wound about the outer surface, or a coating provided about the outer surface (see Fig. 6 and description at col. 12, lines 22-24), for further enhanced radial compliance.

First, it must be pointed out that the present claims require that a porous, essentially PTFE tube is provided with a covering of porous, essentially PTFE film. While the graft of Tu et al. may be provided with a covering of fibers made of an elastic material; the fibers are never said to be porous. PTFE, in contrast, is widely understood to be an inelastic material. More importantly, fibers are not films; fibers are of course typically round in cross section and as such have an entirely different aspect ratio from films which are thin and, in comparison to the thinness, wide. The entirely different aspect ratios result in entirely different engineering properties. Tu et al. never teach or suggest the use of film in any form. The only place the word "film" appears in Tu et al. is at col. 1, lines 46-52 wherein the use of reinforcing films with prior vascular grafts is acknowledged. This passage states that such films are undesirable because they slow down tissue ingrowth, prevent rapid healing and cause these vascular grafts to be stiff and non-compliant to the natural artery. Tu et al. not only do not teach or suggest the use of films in their graft construction, they clearly teach away from the use of films. Accordingly, this reason alone is sufficient to conclude that Tu et al. cannot be said to anticipate the present claims.

The Examiner asserts that (Fig. 2) Tu et al. teach a tube with an outer covering and that the graft tube is made of PTFE and has a covering that is "essentially polytetrafluoroethylene" (col. 3, lines 45-46 and Abstract). He adds that he is interpreting

"essentially" as a comprising clause that does not exclude other materials and that it is understood that a large amount can be understood to be encompassed by this. He adds that Tu et al. disclose "that when a blend of PTFE is used that the majority is 95% PTFE (col. 14, lines 15-20) and can thus be considered "essentially" PTFE."

Applicants strenuously disagree with the Examiner's interpretation of "essentially polytetrafluoroethylene." The presence of the elastomeric components in Tu et al. are clearly essential; they are admittedly responsible for the compliant behavior of their vascular graft construction. See col. 10, lines 9-11. At col. 13, lines 15-26 they compare a GORE-TEX Vascular Graft with their PTFE/elastomer composite graft and demonstrate enhanced radial compliance that is due to the presence of the elastomeric components. The present invention does not require materials other than PTFE to achieve the stated performance re distensibility under increasing pressure to a second circumference beyond which the tube is resistant to further dilatation if used within the designed operating range of pressures. Other materials may be present to the extent that they do not interfere with this performance characteristic, hence the essentially PTFE limitation.

The Examiner appears to have created his own interpretation of "essential." "Essential" clearly has nothing to do with relative proportions of primary and secondary materials but rather with the effect that the presence of the secondary material has on the behavior of the resulting composite. There is considerable precedent for this, even if "essentially" is used without the entire phrase of "consisting essentially of."

> "The word "essentially" opens claims to the inclusion of ingredients that would not materially affect the basic and novel characteristics of appellant's composition as defined in the balance of the claim." *In re Janakirama Rao*, 317 F.2d 951, 137 U.S.P.Q. 893, 896 (C.C.P.A.1963).

Clearly, the presence of the elastomer in Tu et al. is not merely incidental and as such does not anticipate the "essentially polytetrafluoroethylene" language of the present claim 1.

The Examiner further asserts that Tu et al. disclose that the graft circumference increases as a result of blood pressure, col. 5, lines 46-48.

This citation states that "As blood flows through the graft the inherent elasticity provided by the fibers applied under tension minimizes the dilatation of the graft." This statement describes that while dilatation can occur in small amounts, the intent of the elastomeric component is to *minimize dilatation*. It certainly does not suggest a tubular graft capable of at least 100% dilatation. Further, at col. 13, lines 15-26, Tu et al. describe that their tubular graft exhibits a compliance range of 5.2×10^{-2} %/mmHg, referring to the effect that blood pressures can be expected to assert on the diameter of the vascular graft. For a very high blood pressure of 150mmHg, this amount of compliance would result in a diameter increase of 1.5% above the nominal tube diameter at zero pressure, an amount that cannot be considered to be suggestive of the 100% diameter change requirement of the present claims.

The Examiner also asserts that "Tu additionally discloses that the tube can be expanded such that the second circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col. 10, lines 34-38."

First, this passage of the Tu et al. specification is describing step 6 of a nine step manufacturing process. It is teaching how to modify a precursor tube, by pushing a mandrel of larger diameter than the tube through the precursor tube, which is far from being a completed vascular graft. Because this is a manufacturing step of a precursor component, it does not anticipate the present claims to a blood conduit liner.

Secondly, this passage states that "the inside diameter of the tubing, which is normally about 4mm to about 8mm, is radially expanded to be about 6mm to about 10mm. A reader would clearly interpret this as meaning that a 4mm tube might be enlarged to 6mm and an 8mm tube might be enlarged to 10mm. The Examiner's reading of this as meaning that a 4mm tube might be enlarged to 10mm is entirely unreasonable. Further, see Tu et al. at col. 8, lines 43-47 that describes the same diametrical expansion: "The radial expansion of the inside diameter of the tubing may increase from about 5% to about

50%, preferably about 10% to about 50%. For example, if the inside diameter of the inner layer is 4 mm, it may be increased to 6 mm." The Office has previously asserted this same argument without acknowledging Applicants' specific response; a reply to this specific response is respectfully requested in the event the argument is not found persuasive.

The Examiner next asserts that, with regard to Tu et al., "The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon." Applicants do not take issue with the PTFE microstructure of the tube of Tu et al., but note again that elastomers are additionally required with this vascular graft. We find no basis in the specification of Tu et al. for the Examiner's conclusion that the circumference of this vascular graft is fully capable of being increased by inflating a balloon. As a vascular graft having a nominal diameter, it is not intended to deviate appreciably from that diameter (see the appended declaration of James Lewis). Note the specification at col. 5, lines 46-49 that teaches that the Tu et al. vascular graft is intended to be dilatation resistant. While one might inflate a catheter balloon within the Tu et al. graft and achieve some degree of dilatation, there is no reason to expect that 100% dilatation might be achieved without rupture of the graft. Further even if it were to reach 100% dilatation, there is no reason to expect it to have a second circumference at which it would resist further increases in diameter. Indeed, as the diameter of this graft increased, one of ordinary skill in this art would expect the wall thickness of the graft to decrease with increasing circumference and thereby become increasingly weak as the circumference continued to increase, until failure by rupture occurred.

The Office concludes by stating that "Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited."

This conclusion was addressed above when also asserted with regard to the Myers et al. reference; the same arguments presented with regard to Myers et al. also apply to Tu et al. Applicants have shown that the claimed invention does not reside in, and is not anticipated by, either Myers et al. or Tu et al.

Rejections under 35 U.S.C. §103

I. Claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Eilentropp (US 4,791,966, hereinafter "Eilentropp").

Tu et al. are discussed above. Eilentropp teaches the helical wrapping of a ribbon of PTFE about a cylindrical form (e.g., a wire or a removable mandrel) followed by fusion of the overlapping edges of the wrapped ribbon. The ribbon has a lens or trapezoidal cross section in order to minimize the thickness of the resulting tubular form. The tape of Eilentropp is never suggested to be a porous material, nor is it suggested that it might be useful for medical implants

The Examiner states that Tu et al. disclose that layers of film applied to the tube are helical, but that they do not disclose that the PTFE layers are helical, referring to col. 11, lines 7-11 and col. 12, lines 1-4. These passages of the Tu et al. specification refer to winding elastic fibers (*not* film, not porous and not of PTFE). As noted above, Tu et al. never teach or suggest the use of a film or more specifically a helically wrapped film, and indeed, clearly teach away from the use of film (col. 1, lines 44-52). As such, one of skill in the art, on considering Tu et al., would not substitute the helically wrapped, overlapping inelastic non-porous PTFE tape of Eilentropp for the elastic fibers of Tu et al.

Further, these fibers are wound so as to provide gaps or large pores between the adjacent windings (Tu et al. at col. 12, lines 1-6, see also Figure 8). The gaps between provide porosity to the resulting vascular graft.

The helically wound ribbon of Eilentropp is provided with overlapping adjacent edges. The ribbon is PTFE, but is never suggested to be porous PTFE and hence can be taken to result in a non-porous tube following fusion of the overlapping edges. This resulting non-porous tube would be entirely resistant to any dilatation. Further, the necessary porosity of the Tu et al. graft would be lost if the teachings of Eilentropp were combined, ruining the vascular graft of Tu et al. for its intended purpose. Still further, one of skill in the art of making vascular grafts, in considering a teaching that requires helical wrapping of an elastic fiber with gaps between adjacent windings to make a porous graft with a degree of diametrical compliance, would not look to a teaching of an overlapping helical winding, would not look to an overlapping film in place of a fiber, would not look to inelastic PTFE to replace an elastic component, and finally would not look to a teaching that results in a non-porous tube and a non-compliant tube. There is simply no reason to combine these two references.

All arguments above (pertaining to anticipation of claim 1 with regard to the Tu et al. reference) also apply to this rejection. For all of these reasons, this combination does not suggest the present invention.

II. Claims 18 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Hughes et al. (US 4,728,328). Tu et al. are described above. Hughes et al. teach a cuffed tubular organic prosthesis. The Examiner notes that Hughes teaches an embodiment (Fig. 12) having three ends (a bifurcated graft). Applicants acknowledge this, but contend that these two references in combination do not suggest the present claimed invention for all of the reasons described above in the arguments pertaining to anticipation of claim 1 by the Tu et al. reference. It is noteworthy that neither reference suggests a diametrically expandable graft (to a limiting circumference) of essentially PTFE. The present reference is not suggested by this combination.

III. Claims 3, 4, 15, 16, and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu et al. in view of Lee (US 5,123,917).

Tu et al. is described variously above. The Examiner notes that Tu et al. do not teach the possibility of a wall thickness of less than 0.1mm, and that Lee teaches the thickness of his graft is equal to about 0.1mm (col. 5, lines 56-59) and that Lee additionally teaches that a stent is used to secure his graft to a blood conduit (col. 5, lines 25-31).

Again, all of the arguments presented above pertaining to the anticipation of claim 1 by Tu et al. are applicable here. Further, the combination of Tu et al. with Lee will still require the elastomeric components of Tu et al. that are fundamental. As such, the resulting graft would not be "essentially PTFE." This combination does not suggest the present invention.

Conclusion

For the foregoing reasons, the present invention is neither taught nor suggested by any of the references of record. Accordingly, Applicants respectfully submit that these claims are now in form for allowance. If further questions remain, Applicants request that the Examiner telephone Applicants' undersigned representative before issuing a further Office Action.

Respectfully submitted,

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